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EDITORIAL COMMENT

The Cardiologist's Toolbox: Improving Care*

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When patients seek medical advice and care, they assume that their physicians will apply the latest scientific information to both their diagnosis and treatment (1). And although "evidence-based medicine" may not yet be a common phrase in the waiting room (2), the increasing availability of medical information, through both the traditional media outlets and the Internet, will only undoubtedly increase the rightful expectation of patients to receive the best care possible.

Cardiology as a specialty has been particularly blessed by the availability of evidence-based medicine. Indeed, the advent of the large-scale, placebo-controlled trial has been a particular cardiology phenomenon. The care of acute myocardial infarction (AMI) has been revolutionized by the adoption of revascularization strategies (both thrombolysis and primary percutaneous intervention) for ST-segment elevation myocardial infarctions (STEMI), as well as secondary prevention strategies. The latter include antiplatelet therapy (particularly aspirin), beta-blockers, angiotensin-converting enzyme inhibitors, lipid-lowering therapy (particularly statins), along with crucial lifestyle modifications, such as diet intervention, exercise, and smoking cessation (3). It has been estimated that the additive effects of these interventions can lead to an 80% reduction in events (4).

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The use of aggressive lipid-lowering therapy for secondary prevention after myocardial infarction (MI) illustrates the marked changes that have occurred in the past two decades. Initially viewed by physicians with skepticism (5), the results of landmark clinical trials, including the Scandinavian Simvastatin Survival Study (4S) (6) and Cholesterol And Recurrent Events (CARE) (7) trial, firmly proved the importance of lipid-lowering therapy for secondary prevention. Recently, the 20,536-patient Heart Protection Study (8), which included 3,421 patients with low-density lipoprotein (LDL) <100 mg/dl at entry, showed similar reductions in cardiovascular events compared with patients with higher LDL levels, thus extending the benefit to patients who until recently were not considered candidates for therapy.

Although the findings of the Heart Protection Study have not yet been incorporated into national guidelines, the current American College of Cardiology (ACC)/American Heart Association (AHA) AMI guidelines, as well as the cholesterol-specific Adult Treatment Panel III guidelines of the National Cholesterol Education Program, already provide a clear mandate to treat post-MI patients aggressively for secondary prevention. Yet despite these guidelines, numerous studies (9,10) continue to document significant treatment gaps. The continued deficiencies in the health care system, epitomized in the lack of adherence in post-MI care, has led the Institute of Medicine in 2001 to label the problem as not only a quality gap but a "quality chasm" (1).

The realization that without significant improvement in the implementation of prevention strategies, particularly in the high-risk secondary prevention population, we will not make significant headway in lowering the morbidity and mortality of coronary disease, has led various organizations to both point out the problem as well as initiate programs to try to close treatment gaps. In this endeavor, credit is due to the pioneering efforts of Dr. Greg Fonarow, who in 1994 launched the Cardiac Hospitalization Atherosclerosis Management Program at the University of California-Los Angeles, to improve compliance with post-MI care (11).

Both the AHA and the ACC have launched initiatives aimed at improving the implementation of secondary prevention therapies. Both organizations have rightfully chosen the hospital environment for the initial efforts because the hospitalized MI patient represents the "low-hanging fruit." Moreover, studies have indicated better compliance when therapies are initiated during the index hospitalization (12).

The contribution of the ACC to this important quality issue is the aptly named GAP projects, for Guidelines Applied in Practice. Initially piloted in Michigan three years ago, the project has now been extended to several states. One particularly important finding from the pilot study was an association between the use of standardized AMI orders and improved adherence to early quality indicators, such as the administration of aspirin or lipid measurements within 24 h of admission. Similarly, the use of standardized discharge orders was associated with excellent adherence (80% to 90%) to late indicators, such as the use of lipid-lowering drugs, aspirin, beta-blockers, angiotensin-converting enzyme inhibitors, as well as lifestyle counseling. Unfortunately, the use of these tools was documented in only one-quarter of the patients (13).

The follow-up GAP study in Michigan, which is reported in this issue of the *Journal* by Mehta et al. (14), therefore focused on increasing the use of tools, such as care pathways, standardized AMI admission, and discharge orders. Significant efforts were made to educate providers (both physicians and nurses), identify barriers, and assemble a multidisciplinary team that would be able to impact the process of care in the hospitals.

On the whole, the findings are gratifying: use of at least one tool increased to 93% of patients and, as predicted, tool

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use was associated with increased adherence to the guidelines. Notable exceptions include low rates of adherence in patients undergoing bypass surgery, with only one-half of post-coronary artery bypass grafting (CABG) eligible patients receiving a statin. Even in the non-CABG patients, significant areas for improvement remain: whereas standard admission orders were used in 82% of patients overall, standard discharge orders were used in only 47%.

Disease management efforts are time-consuming and tedious, and for many lack the excitement of traditional new scientific discovery, whether clinical or basic. However, it is also self evident that treatments not prescribed remain of only theoretical benefit. Therefore, the authors and members of the AMI GAP project should be congratulated on both their devotion and success.

There are some important limitations, however, to both this particular study as well as other attempts at disease management. The study by Mehta et al. (14) used historical controls from approximately one year earlier. During this time period, physician adherence to AMI guidelines may have increased independently of the intervention. The study, however, again confirmed an association between the use of standard tools and quality indicators, suggesting that indeed the improvements observed were to a large degree the result of the initiative itself. More importantly, the data are only indicative of prescribing patterns up to discharge, and long-term compliance is not assured.

More fundamental questions arise in considering the impact of guidelines in general and their role in clinical medicine. Although undoubtedly the implementation of evidence-based medicine can improve the health of the population targeted as a whole, individual results may differ. The effect of an intervention may be known on a population basis but always remains an "experiment in regard to the well-being of that individual patient" (15). Indeed, the trend toward standard guideline-based medicine is, in some respects, in direct conflict with another vision in medicine—the vision of individually targeted therapy based on our individual uniqueness. The case of statins is illustrative. Although the overall benefit of statins is unquestionable and does not even appear to be dependent on baseline LDL levels, data from one of the landmark studies, the 4S study, suggests that not all patients benefit equally. In the 4S study patients who were hyperabsorbers of cholesterol, as determined by higher blood cholestanol levels, did not appear to benefit from the use of simvastatin (16).

The critical physician/scientist may also question whether specific therapies, endorsed with broad strokes, are applicable to today's patients. Acute use of beta-blockers are endorsed in the guidelines for every AMI patient without clear contraindications, such as bradycardia or asthma (3). Yet the trials that these recommendations are based upon were performed before the era of revascularization. In the setting of primary percutaneous coronary intervention for STEMI, there has been little prospective randomized data available (17), although three retrospective articles (18–20) recently published in the *Journal* point to a potential benefit. Similarly, the long-term benefit of beta-blockers in low-risk patients, particularly those who have undergone complete revascularization, is still unclear, despite the overall endorsement by the guidelines (as a class IIa indication). Data from the Beta-Blocker Heart Attack Trial (21), performed even before the era of percutaneous coronary intervention, actually indicated a lack of benefit in what was defined at the time as "nontransmural MI." Given the potential for significant side effects with beta-blockers (such as impotence, fatigue, and decreased exercise tolerance), there will undoubtedly be situations in which the benefits may not be sufficient to outweigh other considerations such as quality of life.

What is the conscientious cardiologist to do in the face of mounting and overall laudable efforts to standardize care? How does one practice medicine as an art in the age of evidence-based medicine? One critic of evidence-based medicine has warned against "an environment in which numbers, not patients, are treated and in which the best interest of individual patients is subordinated to some statistical standard" (22). Here again, the use of appropriate tools may actually be of help, provided they serve as a reminder and a quality check rather than mandating a certain course of action in abeyance of clinical judgment. In this regard, they should also serve as documentation tools to indicate whether and why a particular evidence-based treatment is either prescribed or withheld.

The AMI GAP project (14) was funded by grants from the ACC and pharmaceutical companies. Although we are not told of the exact cost and a cost-effectiveness analysis is not presented in the report, it is clear that disease management efforts require both tremendous organizational efforts and significant funding, which is often lacking.

Moreover, the present study (14) used a paper-based system. Indeed, the American health care system, with the notable exception of insurance claims, is still woefully behind in the implementation of information technology, lagging far behind other sectors in society. Integrating disease management processes into an electronic medical record, while allowing for the individualization of medical care and incorporation of new scientific information, remains a mighty challenge. The GAP project is an important step in the long road toward quality in medicine in general and cardiology in particular.

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